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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/243,102      | 02/02/99    | MACLACHLAN           | I 16303-73-2        |

020350 HM12/0111  
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EXAMINER

ZARA, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1635

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DATE MAILED:

01/11/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File

# Office Action Summary

Application No.  
09/243,102

Applicant(s)

MacLachlan et al

Examiner

Zara, Jane

Group Art Unit  
1635



☒ Responsive to communication(s) filed on Oct 24, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-34 is/are pending in the application

Of the above, claim(s) 29-34 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-28 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### DETAILED ACTION

This Office action is in response to the communication filed October 24, 2000, Paper No.

7.

Claims 1-34 are pending in the instant application.

Applicant's election with traverse of Group I, claims 1-28, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the two groups stem from a common concept and theory and are thus related. This is not found persuasive because the two groups, while related in concepts and theories, require divergent searches, which searches are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

In accordance, claims 1-28 are examined in the instant Office action as indicated below.

#### Withdrawn Rejections

Rejection of claims 3-7, 11 and 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments filed October 24, 2000, Paper No. 7.

#### Retained Rejections

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention over the scope claimed, for the same reasons of record as set forth in the Office action mailed April 4, 2000, Paper No. 5.

Applicants' arguments have been fully considered but they are not persuasive. Applicants argue that extensive guidance has been provided in the specification for enablement over the scope claimed. Enablement has been provided for the treatment of neoplasia comprising tumor reduction and tumor treatment in various appropriate animal models, which treatment comprises the systemic administration of recombinant "hyper" type 1 thymidine kinase (as described by Black et al, 1996, See page 39 of the specification), which recombinant nucleic acid is encapsulated in the lipid formulations denoted as either 1.1 or 1.2 (See pages 23-24 of the specification), which formulations comprise mixtures of the lipids DOPE, DODAC, and PEG-Cer, of a respective molar ratio of 84:6:10, and which PEG-Cer comprises either PEG-Cer-C8, -PEG-Cer-C14, or PEG-Cer-C20, and which treatment further comprises the administration of ganciclovir also encapsulated in the lipid formulations denoted as 1.1 or 1.2 in the chronology as described in the specification on pages 38-39. The specification does not provide enablement for the treatment of all possible neoplasms in mammals comprising the administration of any and/or all serum stable nucleic acid-lipid particles comprising any and/or all nucleic acids comprising all expressible genes. The specification does not enable the breadth of the invention as claimed, which was discussed in the Office action mailed April 10, 2000.

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*New Grounds for Rejection*

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe elements which are essential to various functions of the claimed invention, which elements include those which are essential to the definition of “gene”, which include naturally occurring regulatory elements, untranslated regions, and/or those elements which mediate the expression of a particular gene in a particular cell type, and which elements are empirically determined and not disclosed. The specification does not describe the elements which are essential to the genera comprising either a portion of a nucleic acid, or a portion of a lipid, whereby the latter fully encapsulates the former. Furthermore, the specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising homologous genes. The disclosure does not clarify what the common attributes are encompassed by portion or comprising homologous genes. Thus, the scope of the claims includes numerous structural variants, and the genera are highly variant

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because a significant number of structural differences between members of a given genus is permitted. Concise structural features that could distinguish structures or compounds within a genus from others are missing from the disclosure. No common structural attributes identify the members of the genus comprising a portion of a nucleic acid, a portion of a lipid, therapeutic polynucleotides, therapeutic polypeptides, or homologous genes. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in each genera such that the common attributes or characteristics concisely identifying members of each proposed genera are exemplified, and, because each genus is highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the various genera claimed. Thus, Applicant was not in possession of the claimed genera.

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be


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retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*JZ*

January 9, 2001

  
ANDREW WANG  
PATENT EXAMINER  
TC 1600